Report of the Advisory Committee
to the Director, National Institutes of Health

Human Fetal Tissue Transplantation Research

December 14, 1988
Bethesda, Maryland

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REPORT OF THE ADVISORY COMMITTEE TO THE DIRECTOR, NATIONAL INSTITUTES OF HEALTH

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DECEMBER 14, 1988

HUMAN FETAL TISSUE TRANSPLANTATION RESEARCH

EXECUTIVE SUMMARY

The Advisory Committee to the Director, National Institutes of Health (NIH), joined by representatives of the National Advisory Councils of the NIH Institutes, met on December 14 to review the Report of the Human Fetal Tissue Transplantation Research Panel. The Panel was constituted as an *ad hoc* consultants group to the Advisory Committee to the Director, NIH, and charged with reviewing the ethical, legal, and scientific issues surrounding the use of human fetal tissue derived from induced abortions in transplantation research. During its review, the Committee heard presentations by nine members of the Panel, including its Chairman, with an additional statement entered into the record without the Panel member being present. The Panel presentations summarized many of the considerations leading to the report and elaborated on some of the reasons for individual Panel member concurrence or dissent. After the Panel presentations, the Committee members and Council representatives discussed the report, inviting comments and further clarification from the Panel members present. Three unanimous recommendations emerged from the deliberations of the Advisory Committee and the Council representatives: (1) to accept the report and recommendations of the Human Fetal Tissue Transplantation Research Panel; (2) to recommend that the Assistant Secretary for Health lift the moratorium on Federal funding of human fetal tissue transplantation research utilizing tissue from induced abortions; and (3) to accept current laws and regulations governing human fetal tissue research with the development of additional policy guidance as appropriate, to be prepared by NIH staff, to implement the recommendations of the Human Fetal Tissue Transplantation Research Panel.

INTRODUCTION

In October 1987, the NIH submitted a request to the Assistant Secretary for Health for the approval of an experimental implant of human fetal cells derived from induced abortion tissue aspirates into the brain of a Parkinson's patient. The protocol was proposed by intramural investigators in the National Institute of Neurological and Communicative Disorders and Stroke. Although this research procedure did not require the approval of the Department of Health and Human Services, the Director, NIH, elected to advise the Assistant Secretary for Health of this proposed research project because of the broad scientific and ethical implications surrounding this area of research.

On March 22, 1988, the Assistant Secretary for Health responded by requesting that the NIH "convene one or more special outside advisory committees that would examine comprehensively the use of human fetal tissue from induced abortions for transplantation and advise us on whether this kind

of research should be performed, and, if so, under what circumstances." At the same time, he outlined a series of 10 questions related to this research issue to guide the panel of consultants in their deliberations. Concurrently, the Assistant Secretary for Health withheld his approval of the proposed experiment and future experiments, pending the outcome of the meeting of a panel of consultants called for the specific purpose of reviewing the legal, scientific, and ethical issues surrounding the human fetal tissue transplantation research issue.

The Human Fetal Tissue Transplantation Research Panel, which was convened as an *ad hoc* group of consultants to the Advisory Committee to the Director, NIH, met three times: September 14-16, October 20-21, and December 5, 1988. The first two days, the Panel heard public testimony from over 50 experts in the fields of science, law, and ethics, including representatives from diverse organizations. After the public testimony, the Panel met for the remainder of the time deliberating among themselves on the questions posed by the Assistant Secretary for Health, drafting responses to the questions, and developing supporting considerations to explain the Panel's rationale in arriving at the responses to the questions posed. All of the meetings of the Panel were open to the public and were well attended by interested individuals and the media.

The Advisory Committee to the Director, NIH, met on December 14 to consider the report of the Human Fetal Tissue Transplantation Research Panel and to provide the Director, NIH, with the Committee's recommendations relative to the content and recommendations contained in the report.

SUMMARY OF PRESENTATIONS BY INDIVIDUAL HUMAN FETAL TISSUE TRANSPLANTATION RESEARCH PANEL MEMBERS

Individual members of the Human Fetal Tissue Transplantation Research Panel had been invited by the Director, NIH, to address the Advisory Committee at its meeting on December 14 to provide the Committee further insight into the deliberations of the Panel. Nine of the ten members of the Panel present at the meeting, including the Chairman, made brief statements that further clarified their work on the Panel or explained their vote on the 10 questions the Panel was asked to address in developing its report. An additional statement by a Panel member was entered into the record without the member being present.

The individual Panel presentations confirmed the wide diversity of convictions, interpretations, and points of view that were reflected in the Panel report. On the question of using human fetal tissue derived from elective abortions for transplantation, the individual Panel presentations described three general positions. One position held that abortion is legal; consequently, the use of the tissue derived from such abortions for research is an acceptable, and even desirable research activity, and is consistent with sound ethical and moral principles. The second position maintained that induced abortion is immoral and that Federal funding of research using tissue from such abortions would institutionalize an immoral activity. As a middle point between these two views was the position that regardless of how serious, or even morally tragic, a decision for an abortion and the action following that decision might be, abortion is presently legal, and the issues

surrounding the abortion are entirely separable from the issues surrounding the use of the tissue in research, provided that appropriate protections are established to guide the research. Each of these three positions was given further support in the invited arguments and presentations by the individual Panel members.

One Panel member noted that the scientific community has long been concerned about the use of fetal tissue in transplantation research, and previous commissions, such as the 1975 National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, have dealt with this issue. However, the underlying "tension" in dealing with this issue revolves not around the science of this type of research, but the manner in which human fetal tissue is obtained--that is, by induced abortions. It is the tremendous polarization of attitudes on abortion that makes public debate on this issue very difficult. It was emphasized that the work of the Human Fetal Tissue Transplantation Research Panel was an excellent illustration of the benefits of such panels and commissions because a forum is created in which rational debate on complex issues is encouraged and fostered.

Another Panel member elected to concentrate on two issues--the morality of using human fetal tissue derived from an abortion and the importance of gaining maternal consent in the donation process. This Panel member's conclusion was that society should not reject using human fetal tissue for transplantation research because the tissue is derived from an induced abortion, since the use of such tissue does not imply complicity in the decision or the act of abortion. On the issue of maternal donation of fetal tissue, the Panel member underscored that it was imperative to protect the right of the pregnant woman to donate her fetal tissue since the abortion request did not negate her rights as a donor of her own tissue.

Two Panel members expressed unequivocal opposition to abortion and characterized the use of human fetal tissue for research as complicity in the act of abortion. They stressed that sanctioning the use of human fetal tissue in transplantation research would serve as a further inducement to pregnant women to abort, because a possible societal good could now be inferred from the use of aborted tissue. Additionally, if therapy using fetal tissue transplantation techniques proves beneficial in treating certain diseases, there may conceivably be an increased demand for fetal tissue that does not keep pace with the supply. This then would represent a further inducement to abort and would result in an increased number of abortions nationally.

Another Panel member pointed out that public policy needs to be based on a moral framework that recognizes the plurality of our society, that is, differences in values, beliefs, and lifestyles, and not on individual moral interpretations. Furthermore, for many moral problems there may exist more than one correct solution, and in developing public policy, open debate of the issues and building consensus is the best approach to take.

Yet another Panel member concluded that the NIH needs to take the lead in this area of research to assure that safeguards and protections are put in place to guide the research efforts of scientists. It was further pointed out

that, despite the moratorium, at least two institutions have recently engaged in privately funded transplantation research using human fetal tissue.

One of the Panel members advanced the argument that it could be considered immoral and unethical for the fetal tissue from induced abortions to be discarded if there is the potential for its positive therapeutic use. Furthermore, using human fetal tissue does not signify approval of abortion, and the Panel member drew the analogy to organ transplantation from homicide and accident victims. Use of organs donated from such sources does not mean that society approves of homicide or encourages accidents.

Finally, one of the Panel members pointed out that while the Panel did not break new ground, it did update the ethical, legal, and scientific discussions on this issue. The report of the Panel was also consistent with the international consensus on human fetal tissue transplantation research developed in eight countries, including the National Health and Medical Research Council of Australia, the British Medical Association, the French National Ethics Consultative Committee for Life and Health, and the Parliamentary Assembly of the Council of Europe. In concluding his statement, this Panel member suggested that the deliberations of the Panel underscored the need for a standing Ethics Board at the Department of Health and Human Services to allow for a recurrent review of fast-changing ethical and scientific issues.

A copy of the full text of each Panel member presentation is located in the Appendix to this report.

DELIBERATIONS OF THE MEMBERS OF THE ADVISORY COMMITTEE AND THE COUNCIL REPRESENTATIVES

In the course of its deliberations, the Advisory Committee recognized that abortion is a moral issue for many in our society, but noted that the Panel was directed to provide advice on what is the appropriate public policy in a single area--the use of post-mortem fetal tissue derived from elective abortions in transplantation research. The Advisory Committee members and the Council representatives quickly concluded that the Panel's report was clearly an impressive and skillfully crafted document, and that given the divisiveness underlying our society on the issues related to the topic under consideration, the report represented a remarkable consensus and praised the Panel for its extensive and thoughtful work. The Committee further concluded that the consensus of the Panel reflected the consensus of the country itself, where widely divergent views are held about the morality of elective abortions and about the use of fetal materials derived from such abortions for the purposes of research.

The Committee then discussed three possible actions it could take relative to the report: (1) accept or reject the report; (2) modify the report; or, (3) write its own report on this issue. After some discussion involving recommending minor word changes in the Panel report, the Committee agreed that it would not reach a different or better consensus in writing another, independent report on this issue. The Advisory Committee then voted

unanimously (19 yea) to accept the report and recommendations of the Human Fetal Tissue Transplantation Research Panel as written.

After its vote to accept the Panel report, the Committee turned its attention to the temporary moratorium on federally funded transplantation research using human fetal tissue from induced abortions issued on March 22, 1988, by the Assistant Secretary for Health. Several Committee members and Council representatives voiced the opinion that they had not read anything in the Panel report or heard any arguments earlier in the day to justify continuing the temporary moratorium. However, several other members requested a clarification on the protections and guidelines currently in place relative to this area of research and also asked what amendments or changes to existing Federal regulations would be necessary to accommodate some of the concerns expressed by the Panel in its report.

In clarifying this issue, NIH staff pointed out that the operative Federal guidelines relative to the transplantation research issue are found in 45 CFR 46. It was further emphasized that these regulations already contain most of the recommendations made by the Panel relative to issues of timing, method, and procedures used to terminate the pregnancy, right of donation, and protection from inducements. These provisions were designed to legally separate the researcher and the individuals who perform the abortion from any relationship to or decisions about termination of pregnancy. It was also suggested by NIH staff, and confirmed by the Director, NIH, that if it was the intention of the Advisory Committee, appropriate NIH staff would make a point-by-point comparison of 45 CFR 46 with the recommendations of the Panel and draft additional policy guidelines if needed. The Advisory Committee urged the NIH not to draft new <u>regulations</u> incorporating the Panel recommendations because the state of the science is changing rapidly and because of the lengthy departmental procedures involved in promulgating regulations that might delay the research process by several years. Furthermore, developing precise <u>policy guidelines</u> would be an effective approach, as they would have the force of regulations and could be developed and implemented within the research community within 2 to 4 months. This latter point was underscored by several Advisory Committee members and Council representatives, with the proviso that any policy guidelines developed presently need to be reviewed and updated as appropriate to keep pace with changes in the science.

It also was pointed out that once the policy guidelines were developed and implemented by institutions and investigators receiving Federal funds for research, compliance with the policy guidelines would be a condition for the receipt of such funds. Several Committee members observed that the existence of strong Federal guidelines usually influences the private sector to follow established Federal procedures in conducting its own research. However, in the absence of Federal direction in this area of research, researchers could continue to obtain human fetal material from induced abortions for their research efforts, but it would be procured without Federal funding or the oversight recommended by the Panel. In addition, the material and the donor would not necessarily have the protections provided in the Federal regulations and policy guidelines.

In these discussions, the Committee briefly reviewed the scientific justification for proceeding with research in this area, including the scientific evidence that intrafamilial transplantation should be prohibited on the basis of current knowledge. It was pointed out that in some disease areas, such as Parkinson's disease and juvenile diabetes, the results of animal studies provide justification for conducting human studies. The Committee was informed that in these disease conditions, first trimester fetal tissue is optimal for transplantation. One Council representative noted that recently the American Association of Neurological Surgeons had formally adopted the position that evidence now exists from animal research that justifies clinical studies on patients with Parkinson's disease. In other disease states such as Alzheimer's disease, Huntington's disease, spinal cord injury, and neuroendocrine deficiencies, experts recommend further animal studies.

The Advisory Committee concluded this portion of its deliberations by voting unanimously (19 yea) to recommend that the Assistant Secretary for Health lift the moratorium on Federal funding of human fetal tissue transplantation research utilizing tissue derived from induced abortions.

There followed a brief discussion among the Committee members and the Council representatives on a variety of issues, including concerns about screening tissue to be used in research to assure that it is disease free; providing selective demographic data to researchers and tissue recipients about tissue donors; insulating a woman's consent to abort from her consent to donate tissue; preventing monetary or other gains for the donation; requiring that procurement agencies not profit from such transactions; reaffirming that the paramount concern in obtaining fetal tissue should continue to be the health of the pregnant woman; and emphasizing that the properties of fetal tissue, such as the optimum gestational age for use in research, should not be a factor in deciding the timing or the procedure of an abortion.

The Committee also raised questions about the details of the Uniform Anatomical Gift Act (UAGA), the Hyde Amendment, and the National Organ Transplant Act as they pertain to this area of research and engaged the Panel members in further discussion. In their responses, Panel members to a great extent reemphasized their earlier views and comments. The Committee was satisfied that if any problems exist, they could be specifically identified and resolved during the drafting of additional policy guidelines.

Finally, the Advisory Committee members and Council representatives voted unanimously for a third time (19 yea) to accept current laws and regulations governing human fetal tissue research with the development of additional policy guidance as appropriate, to be prepared by NIH staff, to implement the recommendations of the Human Fetal Tissue Transplantation Research Panel.

SUMMARY AND RECOMMENDATIONS

The Advisory Committee to the Director, NIH, together with representatives of the National Advisory Councils of the NIH Institutes, met on December 14 to review the Report of the Human Fetal Tissue Transplantation Research Panel. The Advisory Committee heard individual presentations from 9 of the 10 members of the Panel present at the meeting, with an additional

statement entered into the record by a Panel member not present. The Advisory Committee members and Council representatives recognized that abortion is a moral issue for many in our society, but noted that the Panel was directed to provide advice on what is the appropriate public policy in a single area--the use of post-mortem fetal tissue derived from induced abortions in transplantation research. The Advisory Committee members and the Council representatives concluded that the Panel's report represented a remarkable consensus on the issues and praised the Panel for its thoughtful report.

After an extensive review and discussion of the Panel report, the Committee unanimously voted three recommendations:

- to accept the report and recommendations of the Human Fetal Tissue Transplantation Research Panel as written;

- to recommend that the Assistant Secretary for Health lift the moratorium on Federal funding of human fetal tissue transplantation research utilizing tissue from induced abortions; and

- to accept current laws and regulations governing human fetal tissue research with the development of additional policy guidance as appropriate, to be prepared by NIH staff, to implement the recommendations of the Human Fetal Tissue Transplantation Research Panel.

Agenda

Appendix A

AGENDA

58th Meeting of the Advisory Committee
to the Director, NIH

December 14-15, 1988

Building 31, Conference Room 10
National Institutes of Health
Bethesda, Maryland

HUMAN FETAL TISSUE TRANSPLANTATION RESEARCH

December 14, 1988

MORNING SESSION

9:00 Introduction . . . . . Dr. Wyngaarden

9:15 Status Report on Activities Resulting from June 27-28, 1988 Advisory Committee to the Director Meeting on "The Health of Biomedical Research Institutions: Report of the Regional Meetings" . . . . . Dr. Raub

9:30 Human Fetal Tissue Transplantation Research: Overview and Background . . . . . Dr. Wyngaarden

9:45 Summary of September 14-16, October 20-21, and December 5 Meetings of the Human Fetal Tissue Transplantation Research Panel

Overview . . . . . Judge Adams

10:00 Individual Statements by the Human Fetal Tissue Transplantation Research Panel Members

10:00 . . . . . Dr. Ryan

10:05 . . . . . Dr. Walters

10:10 . . . . . Dr. Childress

10:15 . . . . . Dr. Delgado

10:20 . . . . . Mr. Bopp

10:25 . . . . . Dr. Clouser

MORNING SESSION (continued)

10:30 Coffee Break

10:45 Continuing Statements by the Human Fetal Tissue Transplantation Research Panel Members

10:45 . . . . . Ms. King

10:50 . . . . . Prof. Burtchaell

10:55 . . . . . Prof. Robertson

11:00 Summary of Considerations and Recommendations of Human Fetal Tissue Transplantation Research Panel--Scientific Issues

Chairman . . . . . Dr. Ryan

- **Assistant Secretary for Health (ASH) Question 5A: Should there be and could there be a prohibition on the donation of fetal tissue between family members or friends and acquaintances?**

- **ASH Question 5B: Would a prohibition on donation between family members jeopardize the likelihood of clinical success?**

- **ASH Question 9: For those diseases for which transplantation using fetal tissue has been proposed, have enough animal studies been performed to justify proceeding to human transplants? Because induced abortions during the first trimester are less risky to the woman, have there been enough animal studies for each of these diseases to justify the reliance on the equivalent of the second trimester human fetus?**

- **ASH Question 10: What is the likelihood that transplantation using fetal cell cultures will be successful? Will this obviate the need for fresh fetal tissue? In what time frame might this occur?**

General Discussion . . . . . Members, Advisory Committee to the Director and the Human Fetal Tissue Transplantation Research Panel

12:15 Lunch

AFTERNOON SESSION

1:15 Summary of Considerations and Recommendations of Human Fetal Tissue Transplantation Research Panel--Legal and Ethical Issues

Chairman . . . . . Dr. Walters

- ASH Question 1: Is an induced abortion of moral relevance to the decision to use human fetal tissue for research? Would the answer to this question provide any insight on whether and how this research should proceed?

- ASH Question 2: Does the use of the fetal tissue in research encourage women to have an abortion that they might otherwise not undertake? If so, are there ways to minimize such encouragement?

- ASH Question 3: As a legal matter, does the very process of obtaining informed consent from the pregnant woman constitute a prohibited "inducement" to terminate the pregnancy for the purposes of the research--thus precluding research of this sort, under HHS regulations?

- ASH Question 4: Is maternal consent a sufficient condition for the use of the tissue, or should additional consent be obtained? If so, what should be the substance and who should be the source(s) of the consent, and what procedures should be implemented to obtain it?

- ASH Question 6: If transplantation using fetal tissue from induced abortions becomes more common, what impact is likely to occur on activities and procedures employed by abortion clinics? In particular, is the optimal or safest way to perform an abortion likely to be in conflict with preservation of the fetal tissue? Is there any way to ensure that induced abortions are not intentionally delayed in order to have a second trimester fetus for research and transplantation?

- ASH Question 7: What actual steps are involved in procuring the tissue from the source to the researcher? Are there any payments involved? What types of payments in this situation, if any, would fall inside or outside the scope of the Hyde Amendment?

- ASH Question 8: According to HHS regulations, research on dead fetuses must be conducted in compliance with State and local laws. A few States' enacted version of the Uniform Anatomical Gift Act contains restrictions on the research applications of dead fetal tissue after an induced abortion. In those States, do these restrictions apply to therapeutic transplantation of dead fetal tissue after an induced abortion? If so, what are the consequences for NIH-funded researchers in those States?

AFTERNOON SESSION (continued)

	General Discussion	Members, Advisory Committee to the Director and the Human Fetal Tissue Transplantation Research Panel
3:00	Coffee Break	
3:15	Continuation of Discussion of Legal and Ethical Issues	
5:00	Adjourn	

December 15, 1988*

MORNING SESSION

9:00	Consideration of Report and Recommendations of the Human Fetal Tissue Transplantation Research Panel's Report	
	Chairman	Dr. Healy
	Speakers	Dr. Cooper Dr. Palade
	General Discussion and Recommendations	Members, Advisory Committee to the Director and the Human Fetal Tissue Transplantation Research Panel
10:30	Coffee Break	
10:45	Continuation of Advisory Committee Members' Discussion	
12:00	Adjourn	

*The Advisory Committee to the Director concluded its review of the Panel Report on December 14. Consequently, the Advisory Committee Meeting scheduled for December 15 was not held.

Meeting Participants

Appendix B

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Presentations by Individual Members of the Human Fetal Tissue Transplantation Research Panel, December 14, 1988

Appendix C

STATEMENT TO THE ADVISORY COMMITTEE TO THE DIRECTOR, NIH

December 14, 1988

Judge Arlin M. Adams

It is a pleasure to be here, and it has been a great pleasure to serve as chairman of the Panel. I concur with Dr. Wyngaarden that the Panel is broad-based, encompassing many of our disciplines. It was a very fine, courteous, and intelligent Panel. We had many disagreements, but we were never disagreeable.

The voting, as you probably have seen in the material that has been distributed, would favor going ahead with this type of research, but--and it is a strong "but," as far as I am concerned--NIH should do so only with carefully crafted guidelines and an additional provision for periodic reviews, because we are entering into a field where we do not know all of the answers.

As we proceeded with answering the questions that had been posed to us by Dr. Windom--and those questions are in front of you--we thought it insufficient merely to answer the questions, as difficult and as important as that task appeared to us, but to supply the members of the Advisory Committee with explanations or, as we put it, "considerations," which prompted the votes that were taken.

Those considerations appear immediately after the so-called "answers" to the questions. For example, Question 1 is posed and then the response of the Panel and, at the bottom, considerations for Question 1.

Finally, some of the members of the Panel--most of them--believed that we should permit individual members of the Panel to express their views in concurring or dissenting statements. They are immediately behind the answers to the questions and the considerations. I commend them to your attention.

The staff that you made available to us, Dr. Wyngaarden, was most courteous and extremely helpful. I personally am indebted to them and most particularly to Dr. Moskowitz, who was continuously available to us.

We are prepared to continue to assist you and this advisory group, as well as other members of the government as may be necessary to resolve these difficult matters.

STATEMENT TO THE ADVISORY COMMITTEE TO THE DIRECTOR, NIH

December 14, 1988

Kenneth J. Ryan, M.D.

What I am presenting now is a personal viewpoint, which I believe is what each of the Panel participants will be doing until we get to the general discussion of the report itself.

The scientific community has itself been concerned with the ethical issues surrounding the use of cadaveric fetal tissue in transplantation research.

Evidence of this is that I was asked to deliver a lecture on the subject of the ethics of the use of such tissue at an international meeting of neuroscientists at MIT in March of this year. And, ironically, as I was driving home from the lecture, I turned on the car radio, and I heard about Assistant Secretary Windom's moratorium about the use of such tissue.

We are in a sense revisiting the atmosphere of 1974 and 1975, when the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, which I chaired, was formed under the cloud of a congressional moratorium to publicly debate the then even broader issue of fetal research in general. The underlying tension then and now is that fetal tissue can be obtained from therapeutic interruptions of pregnancy or induced "abortions."

Our present Panel, which was formed 14 years later in 1988, like the original commission, was composed of individuals with diverse views and backgrounds. We have had to express these views and debate them in public. It is unlikely that much has been overlooked or omitted in the way of arguments pro or con on the use of cadaveric fetal tissue from abortion.

I personally applaud the tradition of using commissions or panels to work in public under the Sunshine Law and place the debate in a civilized and rational forum so we can deal fairly and democratically with the issues. Unfortunately, when the issue is abortion, we are more polarized than in most public policy debates. And as I have often said, it even stalks the halls of Congress.

There are, however, two legitimate principled positions on abortion itself, which can be defended and should be respected in a democratic society, and these issues are that abortion is moral; that is, a woman should not be forced to remain pregnant against her will; and that, conversely, abortion is immoral and the fertilized egg and fetus have a claim to life, which is absolute.

In any case, for the discussion, our Panel focused on the morality of separating the abortion itself from the use of fetal remains. I believe the only strident and dissonant note to our debate was some panelists who characterized scientists who use fetal remains as being as evil as the doctors who used tissue from the Nazi death camps.

While this has been amply rebutted in the material that has been distributed to you, I do wish to add that the reason the abortion debate is so difficult is that there are no close human analogies to the plight of the pregnant woman who has a conflict with the pregnancy in her body.

I would add that the trend in the last 15 years has been, from a medical point of view, to make abortion safer, quicker, and less expensive for women. There is no evidence that the procedure has been influenced in any way by the uses to which fetal remains are occasionally put, either for teaching or research.

Finally, the decision of the Panel was clear, that transplantation research could and should proceed if the research was kept separate from the decision-making, the techniques, and the economics of abortion, and if it was made non-commercial; that is, set up in a system similar to the transplantation of organs. This is what other countries, like Sweden, have already adopted.

I believe you have a fair report, amply argued, from the Panel, which I wholeheartedly commend to you as a response to Assistant Secretary Windom.

STATEMENT TO THE ADVISORY COMMITTEE TO THE DIRECTOR, NIH

December 14, 1988

LeRoy Walters, Ph.D.

The guidelines on fetal tissue research that are included in our Panel's report constitute at least the ninth set of guidelines formulated on this topic since 1971. Committees or deliberative bodies involved in formulating earlier sets of guidelines represented numerous parts of the industrialized world, including the United Kingdom, the U.S., Australia, the Netherlands, France, Sweden, the Council of Europe, and Canada. There are remarkable similarities in the guidelines formulated in these diverse jurisdictions. In fact, there is an impressive international consensus on the ethical standards that should govern the use of fetal tissue for research. The positions adopted in the Panel's report are located squarely in the middle of this international consensus. We broke no new ground in approving this research in principle or in trying to isolate the research issue from the abortion decision. If we have contributed anything original in our report, it has been to update the scientific, ethical, and legal discussions and to provide a rationale for or explanation of the Panel's recommendations.

There is, of course, no guarantee that the eight committees and the one parliamentary assembly have reached a conclusion that is ethically correct. However, we are less likely to make a serious moral mistake when numerous groups of conscientious men and women from around the world have sought to study an issue with great care and have reached virtually identical conclusions about appropriate public policy.

My second and final comment has to do with the process through which the Panel's report and recommendations have been formulated. We have, I think, been fortunate to be able to arrive at such a substantial consensus in such a short time. We have had a fair-minded and vigorous chairman and a most attentive and diligent staff. The Panel members came from a diversity of backgrounds and represented numerous ethical viewpoints, yet we attempted to treat one another with respect. In some ways, the Panel deviated from the role originally envisioned for it. We held no deliberations in executive session because Dr. Wyngaarden courageously opened all of our meetings to the press and the public. Also, we were asked to finish our work in September, after a single 3-day meeting. In fact, we found it necessary to meet three times, especially if we were to provide an <u>explanation</u> for our recommendations.

Future *ad hoc* panels may not be so fortunate. In my view, the experience of our Panel points up the need for an ongoing ethics advisory committee or board within the Department of Health and Human Services. Ideally, such a body would be able to <u>anticipate</u> important ethical questions that are likely to confront NIH or the Department and to provide counsel that is at once timely, thoughtful, and balanced. Another possible role for such a standing body would be to provide recurrent review for fast-changing issues like the one before us today.

STATEMENT TO THE ADVISORY COMMITTEE TO THE DIRECTOR, NIH

December 14, 1988

James F. Childress, Ph.D.

I am grateful for the opportunity I have had to serve on the Human Fetal Tissue Transplantation Research Panel and to appear here today. The first and fourth questions were two of the most important and divisive questions faced by the Panel. The first question invites us to consider whether the act of elective abortion disqualifies society from using the tissue of the aborted fetus, and the fourth question invites us to consider whether a woman's decision to abort disqualifies her from donating fetal tissue for use in transplantation research.

Regarding the first question, I would stress that different Panel members have very different views about <u>why</u> the act of elective abortion is morally relevant to the use of fetal tissue. Some view abortion as raising no moral problems; others view it as raising moral problems but not as absolutely wrong; and others view it as absolutely wrong. We were not asked to--and we could not--settle this issue of abortion. But whatever one thinks about abortion itself, the <u>moral dispute</u> about abortion in our society makes the source of fetal tissue morally relevant. Society faces a moral question about how to respect divergent views on this important matter. The majority of the Panel held--rightly in my judgment--that the fact that fetal tissue becomes available through an elective abortion should <u>not</u> lead society to reject its use in transplantation research. It is possible to use fetal tissue following elective abortions without complicity in abortions and without directly encouraging abortions.

The fourth question focuses on the sufficiency of maternal consent. The majority of the Panel held that maternal consent is <u>both necessary and sufficient</u> to transfer fetal tissue after an elective abortion (except where the father's objection is known). The Panel chose among several different ways to transfer human tissues: donation (express or presumed); abandonment; sales; and expropriation. The Panel clearly gave priority to transfer or acquisition of fetal tissue through express donation.

But <u>who</u> is the appropriate donor? And, specifically, does the pregnant woman's decision to abort disqualify her from being the donor? The Panel affirmed, and I strongly believe, that a woman who has a legal abortion remains the proper decisionmaker about the disposition and transfer of fetal remains. Societal disputes about the morality of her legal decision to abort should not disqualify her as a decisionmaker about donation. I quote from the Panel's rationale: "She still has a special connection with her fetus, and she has a legitimate interest in its disposition and use. Furthermore, the dead fetus has no interests that the pregnant woman's donation would violate."

Winston Churchill once remarked that democracy is the worst form of government except for all others. His comment is relevant here, too--the alternatives to <u>express maternal donation</u> of fetal tissue have even worse moral features. Of the possible ways to transfer fetal tissue, maternal donation is

the most congruent with our society's traditions, laws, policies, and practices, including the UAGA.

If we accept maternal donation as the best mode of transfer of fetal tissue, all things considered, and if we accept the moral relevance of abortion to the use of fetal tissue, for whatever reason, then it is important to develop procedures to separate as much as possible the abortion decision from the donation decision. And that is what the Panel's various recommendations attempt to do, for example, through the prohibition of remuneration for transfer, and the prohibition of the designation of transplant recipients.

WRITTEN STATEMENT PROVIDED TO THE ADVISORY COMMITTEE TO THE DIRECTOR, NIH

December 14, 1988

Jane L. Delgado, Ph.D.

As the President and Chief Executive Officer of the National Coalition of Hispanic Health and Human Services Organizations, I feel it is important to bring to your attention the reasons why the deliberations of this Panel are of particular relevance to the Hispanic community:

- Almost one-third of U.S. Catholics are Hispanics.
- The majority of Hispanics (85 percent) are Catholic.
- According to a recent study (Henshaw and Silverman, 1988):
  - Hispanics represented 8.4 percent of women aged 15-44 and 12.8 percent of abortion patients in that age category.
  - Hispanic women were 60 percent more likely than non-Hispanics to have an unintended pregnancy terminated by abortion.
- Hispanics suffer disproportionately from diabetes and AIDS--diseases where an effective treatment might be developed from current fetal tissue transplantation research.
- Women's issues, Hispanic issues, and Hispanic women's issues are usually at best ignored and at worst maligned.

These facts were important considerations as we developed answers to the questions raised by Dr. Windom. Our deliberations, although generally collegial, unfortunately, were sometimes filled with not-so-polite accusations by articulate persons who used language to veil their own "feelings" while attacking others who were more candid in identifying "feelings" as the essential underpinning for values and beliefs. Besides these displays, I am also concerned about the inappropriate drawing of historical and situational parallels--most notably those to the Holocaust. Dr. Moscona's statement to this effect should be read carefully.

In summary, over the past several months I have had the opportunity to serve on this committee, review the testimony of experts in a variety of fields, and hear the range of concerns raised by members of this Panel. The answers have been developed by taking diverse ideologies and weaving them into a pattern which will benefit and enhance all of humanity. I concur with the responses developed by the Panel because they represent clearly understood, responsible positions.

STATEMENT TO THE ADVISORY COMMITTEE TO THE DIRECTOR, NIH

December 14, 1988

James Bopp, Jr., Esq.

It is my pleasure to address the Director's Advisory Committee, and it has been, indeed, my distinct pleasure to serve on the Panel, which considered an issue about which there is a significant public interest.

You should note that there is, in fact, no consensus concerning the Panel's report. You will find in the documents prepared by the Panel a majority report of the Panel, and then you will find 11 members of the Panel filing concurrences and 4 members of the Panel filing dissents.

So at least 15 members of the 21-member Panel felt it necessary to explain and elaborate their views, put shadings on the recommendations that have been made by the Panel, some of which I think are important for this Advisory Committee to consider as they consider the majorities' recommendations.

Now, the question posed by the Assistant Secretary, in my view, can be summed up as whether transplantation research using human fetal tissue derived from induced abortion is an acceptable act for sponsorship by an agency of the Federal Government.

I think that the Panel's responsibility here was primarily ethical in nature. Since tissue for transplant was obtained from induced abortion, the essential ethical question before the Panel was whether or not the beneficial prospect of transplantation research is subverted by its association with induced abortion.

Some of the other members of the Panel, including myself, were guided by this ethical principle, that one may not take the life of a human being for the benefit of another human being.

Some of us proceeded on the assumption that abortion is, in fact, the taking of a human life and, thus, is morally objectionable except for the gravest of reasons.

Thus, in this inquiry, one of the ethical questions presented to me and to others of us is: Will fetal transplant lead some women to abort who would not have otherwise done so?

Some of us have concluded that it would, in fact, do so; and, thus, fetal tissue transplantation research, which could lead to this result, should not be funded by the Federal Government.

Now, it is reasonable to expect that abortion would increase, if fetal tissue transplantation became common, as a result of two distinct effects of this successful therapy: first, that it would provide a reason for some women to abort who would not have otherwise done so; and, secondly, that the market forces that can be expected to come into play would ensure that abortion clinics encouraged abortion.

As a preface to this, you have to understand that successful fetal tissue therapy involves an institutional relationship between abortion clinics and those who participate in this therapy.

It involves a contract with abortion clinics, people on site to gain the fresh tissue, consent from the woman, and reimbursement of expenses to the abortion clinic. In other words, the relationship necessitates a constant supply of fetal tissue from future abortions from abortion clinics and assurance that that supply will continue.

This, thus, is not a casual relationship, or an accidental one, but an intentional one requiring the most intimate cooperation between those involved in fetal tissue transplant or their agents who would use the tissue and the abortion clinic.

Now to the two effects. First, if fetal tissue transplant becomes common, this will influence some women to have an abortion. It is well-documented in the literature that ambivalence toward abortion is a common reaction of a woman facing a problem pregnancy.

There is a period of intense anxiety and ambivalence that is often experienced during the 24 hours preceding an abortion. This ambivalence is reflected in the fact that one-fourth to approximately one-half of women aborting find the decision difficult to make.

In addition, in studies of pregnant women who choose to abort and others who choose to deliver their children, approximately one-third to 40 percent of the women, whatever their ultimate decision, were reported to have changed their decision at least once, with women who aborted being significantly more likely to report their decision as a relatively difficult one, to rethink their initial choice, and to regret having to have made that decision.

Some women who make an initial decision to abort will change their minds at the last minute, with approximately 5 percent changing their minds after making an appointment to have an abortion and approximately 1 percent changing their minds at the abortion clinic itself.

Significantly, studies reveal that some 24 percent to 37 percent of women who abort do not make up their minds until just before the procedure. In addition, studies reflect that women, when they decide whether or not to abort, often consider multiple reasons, on the average four reasons, in deciding whether or not to have an abortion.

For those women who are ambivalent about abortion, that is, the 40 percent of pregnant women who have changed their minds at least once or who have found the abortion decision difficult, the pros and cons of the decision were somewhat evenly balanced, regardless of what decision is made. Most women who decide to abort are uncertain and uncommitted in their abortion decision. For them, abortion is a marginal good at best.

We also find that women, regarding their reasons to abort, consider the benefits or concerns of others. Thus, I would submit two facts: one, that if fetal tissue transplantation therapies became common, it would become common knowledge among women who were considering whether or not to abort that fetal

tissue transplant is a possible result of their abortion; and when you add a beneficent reason to the number of reasons that women consider when deciding whether or not to have an abortion, some would abort who would not have otherwise done so.

The Panel does acknowledge this result. The Panel admits that, "Transplantation and research with fetal tissue will become general knowledge" if it becomes successful.

They also acknowledge "that knowledge of the possibility for using fetal tissue in research and transplantation might constitute motivation, reason, or incentive for a pregnant woman to have an abortion."

Thus, I would submit that if fetal tissue transplant therapy became common and successful, that this would necessarily influence women, some women, to decide to have an abortion that would not otherwise occur.

Secondly, we cannot ignore the market forces that would be at work. Based on the testimony that we have heard before the Panel, if this therapy became successful, for instance, for Parkinson's disease or diabetes, the demand would greatly outstrip the supply.

Current levels of abortion can provide only enough tissue yearly for fetal transplant for those two conditions for less than 5 percent of those who would benefit from the therapy if successful. This necessarily would create financial incentives for abortion clinics to encourage abortion, even if they are only receiving reimbursement for their expenses.

Indeed, I would submit that these market forces will ensure what we have already come to know, that no one who is not otherwise obligated to follow NIH guidelines would follow them.

Indeed, as we sit here, fetal tissue transplants for Parkinson's disease is underway and has been conducted at the University of Colorado and at Yale during the period of time of the NIH moratorium, during which we were to develop voluntary guidelines to ensure that this research and ultimate therapy are conducted ethically.

Thus, in my view, abortion can reasonably be expected to increase as a result of NIH-funded research, if the research leads to successful therapies.

Now, let me turn briefly to the Panel report. The Panel does acknowledge that "it is of moral relevance that human fetal tissue for research has been obtained from induced abortion."

They then proceed to recommend guidelines which the Panel says is to prevent encouragement of abortion. But the Panel does not say why. The Panel does not explain why it is that guidelines should be adopted to prevent encouragement of abortion. They do hint, though, at some of the views of members of the Panel.

In one of the Considerations to one of the Answers, the Panel says that a majority of the Panel found "that it was acceptable public policy to support transplantation research from fetal tissue either because the source of the

tissue posed no moral problem"; thus, some members of the Panel did not view abortion as morally objectionable, "or because the immorality of its source could be ethically isolated from the morality of its use in research."

I would submit that those who would support guidelines to prevent the encouragement of abortion, but who do not view abortion as morally objectionable, have adopted an incoherent position. If abortion is not morally objectionable and if there are great benefits to be derived from fetal tissue, why is it that you would not encourage abortions?

Indeed, there is no moral or ethical objection to organ transplant from dead adults, provided proper consent is given, and, thus, we spent a lot of time and money encouraging organ transplant.

It is only if abortion is morally objectionable is it coherence to suggest, as the Panel attempts to, that abortion should not be encouraged to derive tissue therefrom.

Thus, in order to understand the report, it is important to know the view of those supporting its recommendations. And we find that view. In the Robertson concurrence, a majority of the Panel members who supported this report, nine so far, do not view abortion as morally objectionable, on the one hand; and, secondly, are perfectly prepared to disregard certain of these guidelines, if more fetal tissue is necessary for transplantation.

In the Robertson concurrence, a majority of the panelists supporting the report say that "if there were a substantial increase in the number of abortions, it still would not follow that fetal tissue transplantation research and therapy should not occur."

"Given the rudimentary development of early fetuses," up to 6 months old, I would add, "the potentially great benefits to recipients, and the legality of abortion, such transplants might still be ethically and legally acceptable."

A positive effect upon abortion increase is, thus, considered no obstacle to medical progress. The majority of panelists supporting the report are in favor of the guideline to prohibit research on fetuses conceived in order to be aborted for their use as fetal tissue because there appears to be no present need for it in research.

Quoting now from the majority of the Panel supporting the report, "In light of these supply considerations," the restriction is accepted. But, "if the situation changes so that the supply of fetal tissue from family planning abortions proves inadequate, the ban "should be reexamined."

Thus, I would suggest that a majority of the panelists supporting this report do not find abortion morally objectionable.

What conclusions can you derive from this fact concerning the report itself? Well, first, since the report provides no basis for its view that encouragement of abortion should not occur, we do not know the ethical basis upon which that report is based.

Secondly, for those on the Panel who believe that abortion is not morally objectionable, we can only conclude that they are recommending these guidelines as a temporary expedient to gain NIH funding, to gain Federal sponsorship, and to gain government approval for fetal transplantation research and therapy.

In any event, however, the guidelines will not prevent encouragement of abortion, as I have already explained. Thus, the guidelines do not separate the abortion decision from the use of tissue thereafter. That is, in fact, as the Panel acknowledges, inseparable if the research becomes successful.

Thus, it is my view, and some others, that fetal tissue transplant from induced abortion leads to ethically unacceptable results, the taking of a life of one human being for the benefit of another.

And research that can be expected to lead to that result should not be funded by NIH.

STATEMENT TO THE ADVISORY COMMITTEE TO THE DIRECTOR, NIH

December 14, 1988

K. Danner Clouser, Ph.D.

Rather than focus on any of the details of our report, I would rather devote my 5 minutes to a more overarching matter which was never discussed as such by our Panel. I want to comment on the moral framework within which such discussions as the one we are engaged take place. There is no time here to defend the moral point of view I am about to describe, but rigorous arguments are available for doing so.[1]

I would urge the Advisory Committee to view the relevant moral issues before us from a moral framework more universal in scope, more cognizant of our society's plurality of values, beliefs, and lifestyles, and more basic than the special moralities from whom we have now and again heard on our Panel. The moral framework I am urging I believe to be the appropriate stance for decisions in the public arena. It is based on rationality, is applicable to all rational persons, and serves the mutual self-interest of all by deriving its moral rules from rationality. These rules proscribe us from causing specified harms to each other, and thus comprise a moral code which would have universal agreement, since all rational persons would avoid harm unless they had a reason not to.

This basic morality is itself a public policy. It is a policy that applies impartially to all rational persons who meet certain specifiable basic requirements such as being able to understand its moral rules and to act in accord with them. These persons comprise the moral community. It is only within and among this community that morality's demands make sense by having a basis in universal agreement and the means of being carried out. Rational persons do not much agree on what is good, but they do agree on what is harmful, that is, what a rational person would avoid unless he had an adequate reason not to. Consequently, rational persons would espouse moral rules prohibiting harm. It is to the interest of all to do so.

We should note that this basic morality is not to be confused with many other look-alikes. It is not a philosophy of life dedicated to the achieving of chosen goods; it is not an elite club delighting in its own secret rules and rituals; and it is not a religious morality based on metaphysical beliefs which not all persons by virtue of rationality alone would have to accept. Rather it is a basic morality, universal and public, that all rational persons by virtue of their rationality alone would espouse.

Now, from this general account of morality certain observations follow that are relevant to the proceedings and the report of our Panel.

1. This basic morality I have described is what is relevant in a pluralistic society because it deals with that on which rational persons might agree on the basis of rationality alone. It is devoid of

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[1]For example, Bernard Gert, Morality: A New Justification of the Moral Rules. Oxford University Press, 1988.

subjective goals, lifestyles, and metaphysical beliefs on which we could get little agreement.

2. Equally rational and moral persons can disagree on the weighting or ranking of evils (i.e., harms), and, consequently, disagree on their moral judgments about certain matters. This means that for many moral problems there is not necessarily one correct solution. And it is appropriate in those instances to settle a moral issue by consensus.

3. The moral community does not include those beings which do not understand the mutuality of morality nor how or why they should be moral. These beings could be trees, animals, or fetuses. This does not necessarily mean that we may treat those beings outside the scope of morality in any way we please, but it does mean that we have a profoundly different basis for our moral relationship with other rational persons than we do with those outside the scope of the moral community.

4. We in the moral community can of course grant rights to those beings outside. But why would we do that? Perhaps, for example, those beings would suffer, and many of us feel a kinship with those beings and want to avoid their suffering. But whatever our individual or personal reasons for wanting to grant certain rights to those outside, there are no universally compelling reasons as there are for our moral rules which pertain impartially to all rational persons within the moral community. So on these matters of our relationships to those beings outside the moral community we must struggle for consensus and compromise. If we ourselves feel a natural empathy for certain others outside the scope of morality, we might try to convince others to empathize--or we might compromise by agreeing to protect something for which they feel a natural empathy or regard. In short, there is nothing here to compel universal agreement, and equally moral, rational persons can and do disagree. And so it was that our Panel members disagreed, but we compromised, namely, by our efforts to insulate the abortion decision from the research and therapy possibilities--either as a protection for that which we felt some empathy or out of concession to those who did have strong empathetic concerns. This must not be written off as a weasel compromise unbecoming the grand enterprise of ethics. Rather it is an entirely appropriate procedure in areas not amenable to determination grounded strictly on rationality.

5. That there are disagreements on the treatment of those beings outside the scope of basic morality implies absolutely nothing about how we might therefore treat other fellow human beings. We are not on any sort of moral slippery slope whatsoever. Within the community of rational persons it is clearly immoral to cause each other harm--such as depriving them of life or liberty, or causing them pain, or deceiving them. And that is why analogies between what has happened to persons in the past and what is happening to fetuses now will not work.

In summary, in the public arena we must deal with basic morality which is founded on rationality. Certain basic rules follow from that rationality and are applicable to all rational beings within the moral community. And from this moral point of view the majority recommendations of the Panel are moral. However much special interests may see them as immoral, there is a strong and universal basis for regarding the recommendations as morally acceptable while recognizing that equally moral and rational persons can disagree on our relationship to those beings outside the moral community.

Those of us who do have strong empathies and concerns for those outside the moral community can of course continue to build a consensus for those particular interests. But the charge to our Panel is not the appropriate occasion.

STATEMENT TO THE ADVISORY COMMITTEE TO THE DIRECTOR, NIH

December 14, 1988

Patricia A. King, J.D.

I appreciate the opportunity to speak with you today. As I feared when I saw my place in the line-up, many of the points that I wished to make have been more ably made by some who have preceded me, and so I will take this opportunity to depart from what I have prepared to just make a few points.

I would urge the members of the Director's Advisory Panel to adopt the recommendation of the Fetal Tissue Transplantation Panel because I believe that those recommendations represent not only a consensus of the Panel, but perhaps a consensus of broader opinion.

I say "consensus" because the vast majority of the Panel, despite our diverse backgrounds, views, and perspectives, were able to reach an agreement on the wording of recommendations and the wording of the considerations that we gave you.

That is not to say that we would not all have wished to have written our precise views and considerations, and some of us, indeed, tried to do that, in concurring opinions and dissents. But I emphasize that the document that you have before you does indeed represent, in my view, well-thought-out recommendations that the vast majority of us could indeed agree with.

There are a few additional points that I would like to make. I chose to speak today because I believe that the document insufficiently addressed some issues. For me, the document insufficiently pointed out the analogy between research with fetal tissues and organ transplantation, which is an accepted therapeutic procedure in our society.

It is no surprise that we ignored or gave insufficient attention to the organ transplantation analogy, since we were asked to respond specifically to ten questions.

Every good lawyer knows that the person who asks the question helps to shape the framework for the answer. That is something that I respect, and I like to think of myself as a good lawyer. But because the questions were worded in a particular fashion, it is no surprise that our answer, in trying to be responsive to our mandate, reflected the particular framework of the questions.

But in being responsive, I would stress that we ignored, in my view, the analogy to existing practices that we, as a society, have found acceptable. I believe that the issue of research with fetal tissue is analogous to organ transplantation. We are talking about using cadaveric tissue.

We are also talking about a very significant and promising area of research. We would not be here if we had not had some indication of the significant benefit that such research might bring. And, indeed, the Panel

heard nothing that would dissuade us of that view. To the contrary, our views have been re-enforced--this is an important and promising area of research.

In my view, because we did not focus on analogies to organ transplantation, we spent far too much time on the question of the association of fetal tissue research with the issue of abortion.

And, as a result, I believe that our efforts to develop principles by which this research might be ethically conducted is too related to the question of whether or not abortion will be encouraged.

I point out to you that the principles that we adopted, the principles of separation, and the ways in which we specify them, are principles that are present in the practice of therapeutic organ transplantation.

It is an area--therapeutic organ transplantation--that we have asked not be commercialized, for example, and our Federal law reflects that fact. Moreover, in therapeutic organ transplantation, we have separated the issues of obtaining organs, and the means by which we obtain those organs, from the question of who will receive the organs and, indeed, under what circumstances those recipients might be designated.

And so I repeat that I think that the guidelines that we have given you would support doing fetal tissue research, in my view, the guidelines are justified, and I would have found applicable if I had not been asked any questions concerning abortion.

Just a few final points. It seems to me that we should keep in mind that we are talking about NIH sponsorship and oversight of fetal tissue research. I emphasize this point because much of our discussion was premised on the fact that this research might prove so promising that other consequences would follow.

But I repeat that we are talking just about research. We do not know what we will find if this research is funded; and finally, it is very important for NIH to take the lead in funding this research, so that NIH can take the lead in setting up the guidelines by which this research will be conducted.

I note that there have been two attempts to do fetal tissue transplantation in the United States already, but I would still emphasize that it is important that NIH be clear about what its role is and about the justification for appropriate guidelines. And I have confidence that the scientific community will voluntarily adhere to those guidelines.

STATEMENT TO THE ADVISORY COMMITTEE TO THE DIRECTOR, NIH

December 14, 1988

Professor James T. Burtchaell

I begin by noting three frustrations. The first is that the documentation resulting from our fall and winter work is substantial, and I am quite sure that the statement and concurring and dissenting documents that were sent to you were crafted with great stress and care, each word having been weighed.

I regret that those documents have been made available to the members of the Advisory Committee for so brief a time before this meeting. For busy people, I am sure it must have been very difficult to find appropriate time to read them and, thus, to appreciate much of what we are going to say today.

My second frustration is that while the questions put by the Assistant Secretary were primarily ethical in nature, a very large part of the response to them was based, not upon ethical, but upon legal, considerations.

And a great deal of that was done simply by setting aside the prospective victims of this research--that is, the aborted children--by simply excluding them, as has been said, from the moral community.

We always exclude from the moral community whomever we wish to exploit. The Fourteenth Amendment had to reverse one instance of that activity. The Nuremberg Code was a more recent rectification of that.

My third frustration regards something that we never spoke of. There would not be the human fetal tissue in such abundance available were it not for the 1973 Supreme Court decisions. Those decisions struck down existing legislation in 50 States and Federal legislation as well, and they have been severely criticized by very serious jurists.

Public opinion polling for the last 30 years demonstrates that there has not yet been a majority of public opinion in support of abortion on demand. And for the National Institutes of Health to presume that this is a dependable source of tissue for the indefinite future strikes me as improvident.

Four of the panelists strongly disagree with the primary recommendation of the Panel. I speak as one of them. I speak on behalf of three of our objections very briefly.

There is, first of all, no person who can fulfill the Nuremberg requirements for authentic voluntary consent. Consent to donate remains can be made by a human being in prospect of death or by someone who has custody of that human being: a parent of a minor child, a court-appointed guardian, a person given power of attorney. That power is only awarded for one purpose: protective care. It is quite clear that the act of abandonment implied in the abortion decision terminates such a trust, and it <u>is</u> a trust.

Therefore, in prospect of the unborn offspring's death, the mother has forfeited, or abrogated, her power to make such a decision on behalf of the still living child.

After death, the next of kin has a right, morally and usually legally, to dispose of their remains, no longer merely for the care of the now deceased unborn, yet, in conformity with the respect due to that deceased human.

The proposal of the Panel is almost unprecedented, to give that uniquely ante-mortem decision over another's remains to another human being, not as a caretaker, but as a person pursuing her own interests, and that is the explicit explanation given by a majority of those supporting this decision.

We have almost no antecedent for that except chattel slavery, and chattel slavery, even in the United States, never gave that large a selfish power over the one who was in control.

Our second objection is that, despite the attempts of the Panel to segregate the moral implications of abortion from the potential therapeutic usage, it does not work.

It is the same argument used by a banker who is laundering funds from drug transactions already completed. The function of the banker in no way affects those transactions, because they already took place. They would have taken place without the banker there ready to launder the funds. Nevertheless, the banker is an accessory: he is complicit by this institutionalized arrangement of interaction and association with those in the drug industry.

The more potent analogy, which is indeed distasteful to a number of our colleagues, comes from the very root of all contemporary literature on the protection of human subjects of research. One of the outrages brought to light in the medical trials at Nuremberg was the research use of cadaveric remains with the same disregard for victims we discern in the programs proposed to the Panel--because they were considered outside the moral community.

The explicit rationalizations given by the scientists engaged in that usage were, if not word-for-word, at least meaning-for-meaning, replicated in the justifications given for present fetal tissue research: "We had nothing to do with the source. Therefore, it is not a concern of ours." On the contrary, we argue that there is indeed complicity after the fact.

The third of our arguments has already been dealt with by Mr. Bopp: that for women facing the excruciatingly difficult and very ambivalent decision to abort, the prospect of bringing good out of tragedy, as they would see it, is going to be not insignificant.

And the financial incentives for those for whom abortion has now become an industry--practitioners who, in largest part, have already moved aside from the mainstream of the obstetrical profession--will prove to be, in its own right, a strong incentive.

We worked a great deal of time on our dissent. I hope that the discussion time provided throughout the rest of this meeting will allow us the opportunity to respond to the questions that it should naturally provoke.

STATEMENT TO THE ADVISORY COMMITTEE TO THE DIRECTOR, NIH

December 14, 1988

John A. Robertson, J.D.

At the risk of sounding redundant, I would like to make a point that I do not believe has been made. The point is about burden of proof. Given the likely benefits of fetal tissue transplant research, the burden of showing that such research should not occur falls--and should fall--on its opponents. In the view of the Panel, the opponents have not met that burden.

The Panel's position recommending NIH support of fetal tissue research is based on the fact that more than 1.5 million elective abortions occur annually in the United States. Because this tissue will be available regardless of research needs and will otherwise simply be discarded, tissue from these abortions can be used for transplant research without involving researchers or recipients in the abortion itself. Indeed, one could reasonably argue that it would be unethical to discard this tissue rather than use it in research that could save many lives.

In making use of fetal tissue from induced abortions, the Panel has recommended a number of safeguards to assure that research needs do not influence the abortion decision. These include postponing requests to use the tissue until after the decision to abort has been made, prohibiting donations to family members, and prohibiting money payments for fetal tissue donation.

The Panel's view is that with these safeguards NIH support for fetal tissue transplant research would not signify approval of or encourage abortion or involve the Federal Government in supporting abortion. It simply recognizes the reality that abortions occur in large numbers, and that once having occurred, there may be better uses of fetal remains than incineration. The most relevant parallel is solid organ transplantation, which makes use of cadaveric organs from accident and homicide victims, without encouraging or approving the actions that make the organs available.

Given these considerations, persons who oppose NIH support of fetal tissue research should have the burden of showing that such great harm or such clearly unethical practices would result that the benefits of fetal tissue transplant research should be foregone. To that end, opponents claim that federal support of any fetal tissue transplant research will necessarily lead to more abortions, and that any increase in abortions, no matter how small or marginal, makes the program causing that increase unacceptable.

After careful consideration the Panel has found unpersuasive the notion that women, who otherwise would have decided not to abort, will choose to abort because tissue may be anonymously donated for research or therapy. The Panel heard no convincing evidence that a pregnant woman's decision against abortion would be changed by the prospect of anonymous tissue donation. The recommended safeguards further lessen the possibility of such influence.

To argue otherwise, as opponents do, requires a different perception of the motivations of women contemplating abortion and of the efficacy of the

recommended safeguards. But it also requires a further assumption--the assumption that federal research support will make fetal tissue transplants so successful and widely known that the prospect of anonymous tissue donation will inevitably alter the decision of pregnant women contemplating abortion.

But the assumption of widespread success, on which the opponent's claim of influence on abortion decisions rests, is itself highly questionable at this very early stage of clinical research. As you well know, there is no certainty or guarantee that fetal tissue transplants will work for any disease, much less that they will be successful for all diseases for which they offer hope. If they are successful, it may be that they will be successful only for certain patient subgroups, or that fetal tissue transplants will be a temporary way station to development of cell lines or biochemical substitutes that in 7-10 years replace fetal tissue transplants totally.

Nevertheless, opponents would ban all federally supported fetal tissue research at this early stage, and thus cut off further investigation that could lead to important findings in many areas, out of the hypothetical fear, which the Panel has rejected, that abortions will increase if the "best case" scenario of widespread success occurs. They would thus prevent federally sponsored research which may have little or no effect on abortion decisions, yet significantly help subgroups of patients. Indeed, they would even prevent the research that might lead to cell lines and other substitutes for fetal tissue, because of the speculative fear that "some" increase in abortions might occur if fetal tissue transplants were a stunning success.

But even if fetal tissue transplants turn out to be a stunning success, the opponents have presented no persuasive reasons to think that that success would have a <u>substantial</u>, as opposed to a <u>minor</u> or <u>marginal</u>, impact on the incidence of abortion. It is not enough to show that there will be <u>some</u> increase in the number of abortions that would not otherwise have occurred from widespread use of fetal tissue. Opponents have the burden of showing that the increase would be <u>substantial</u>, indeed, so substantial that the great benefits that may be possible from fetal tissue research should be foregone to avert this increase. None of the dissenting statements address the size of impact which they speculate would occur, arguing only that <u>some</u> increase or <u>an increment</u> in the number of abortions would result. Apparently their premise is that any increase in abortion, no matter how small, would render fetal transplants unacceptable.

Thus they are in the position of saying that any public policy that has the risk of increasing even slightly the number of abortions at some future time is unacceptable, regardless of the benefits to chronically ill patients. Needless to say, such a position applied to other public policies would ground or stop most progress, since many policies, from building roads, bridges, and airports to approving drugs, may cause the loss of human lives that would not otherwise have occurred--and not just fetal lives. In the case of policies that permit knives and guns to be sold, some of the increased deaths will be intentionally caused.

It is for these reasons that the Panel finds that persons opposed to fetal tissue transplant research have not met the burden of showing that such great harm or such clearly unethical practices would occur that such research should not go forward. Given the great good that is possible from fetal tissue research and the large number of abortions that will be occurring regardless of

tissue transplants, the Panel has found that it is acceptable public policy for the NIH to support such research, and recommends that this Advisory Committee so find as well.

Comments Prepared by Dr. George E. Palade on the Report of the Human Fetal Tissue Transplantation Research Panel

(for the record)

Appendix D

COMMENTS ON THE REPORT OF THE HUMAN FETAL TISSUE TRANSPLANTATION RESEARCH PANEL

George E. Palade, M.D., Yale Medical School

In trying to provide answers to the questions raised by Dr. Windom, the Assistant Secretary for Health, the Panel on Human Fetal Tissue Transplantation Research had to deal with a difficult set of problems. So difficult that it was not possible to concentrate mostly, if not exclusively, on the central pertinent issue: to wit: Should the NIH support research on human fetal transplantation for experimental purposes, primarily for potential therapeutic applications?

The scope of the discussions was enlarged to include the much wider and currently divisive issue of the morality of abortion. This move by part of the members of the Panel generated minority opinions written with eloquence, zeal, and determination, but not always based on unquestionable arguments.

The key issue is the status of the human fetus. Is it a human person entitled to personal protection against everybody (including the prospective mother)? Is it a person whose rights are guaranteed by the Constitution of this country? In fact, a human fetus is not yet a person; it is a person in the making, and the time when it becomes a human person is still a matter of debate and argument.

This uncertainty explains, I believe, the decision of the Supreme Court in the widely known and so often discussed Roe v. Wade decision. Be it as it may, that decision is now the law of the country. Questioning it as immoral implies that we have an amoral or immoral Supreme Court. People may criticize the Court or disagree with some of its decisions, but I wonder how many are ready to label it immoral.

Equating abortion with feticide and feticide with homicide may generate impressive prose but leads to obvious inconsistencies. If feticide is homicide, why are the doctors performing the abortions not put on trial? And why are the women who become accessory to those crimes not treated accordingly?

If more than one and one-half million voluntary abortions are performed every year in this country, we should conclude that something is amiss in our society. The families, the churches, the synagogues, the schools, the media, and our system of health information and assistance are failing in their mission by that large figure. Addressing the causes that create and maintain this unhappy situation is an area in which zeal and crusading spirit would be most welcome.

Another issue of equal importance is the fate of those one and one-half million infants born, but unwanted by their mothers, if abortions become effectively forbidden. Is our society ready and willing to take care of them? We seem to have problems with the health maintenance, proper nutrition, and adequate education of those who are not unwanted.

By comparison with these major issues, the argument about the morality of the use of fetal tissue in transplantation experiments loses strength. The causes and the consequences of the current unhappy situation must be addressed.

Prevention of immorality or questionable morality, like prevention of disease, should be better than cure.

Notwithstanding its limited reproductive capacity, the human species has succeeded in performing the equivalent of a biological miracle: It started by being an endangered species and remained so through millennia, but the situation changed drastically over the last century. At present, Homo sapiens endanger all other species, itself, and the environment. It is clear that mankind does not need more numbers. It needs improvements in the quality of life, be it at the simple nutritional level in underdeveloped countries or at the level of broad education, ethics included, in economically advanced communities.

Perhaps some of the dogmas with which we have to cope in our time reflect our past condition as endangered species. Conceived by men or inspired by God, they responded to the needs of that condition: They were designed to make sure that the species loses as few individuals as possible.

Conditions change and so do dogmas, but they do not change in phase. Dogmas are slow in changing. In 1633, Galileo Galilei was condemned by the Catholic Church for heresy, obliged to deny his discoveries, and stop teaching. He also had to promise that he would denounce all who supported his ideas. Last year, the Church rehabilitated Galileo and recognized that back in 1633 he was right and the Church was wrong.

To redress the damage done by the dogma, it took 250 years, more than compelling evidence, and a courageous Pope. But the rehabilitation came much too late to do Galileo any good as a person. In a less formal way, the same applies for the victims of inquisition in Western Europe from the 15th to the 17th centuries and for the victims of the witch trials in the New England of the 17th and 18th centuries. Perhaps in a century--or less than a century--mankind will look at our current problems with a different understanding.

It does not mean, however, that dogmas must be altogether discarded. They are, in fact, an important element in the continuity of our civilization. They have done, in the past, more good than harm for us. Moreover, we should understand that dogmas have a hard time in periods of rapid change. We should help bring them closer to the realities of the human condition in our time.

Notwithstanding dissentions, abstentions, lively discussions, and passionate prose, the Panel provided useful answers to Dr. Windom's questions. The answers, supported by a large majority of the Panel's members, recommended that the NIH support experimental work with human fetal cell or tissue transplants; it identified the disease in which transplantation is expected to be beneficial (parkinsonism and juvenile diabetes, primarily), and defined in significant detail the conditions under which cadaveric fetal tissue should be collected and independent consent be obtained for its use in research from the pregnant woman. The conditions are designed to preclude commercialization of fetal tissue transplantation and to insure, within possible limits, that therapeutic use will not encourage more women to undergo abortion.

Of course, the entire development is built on a premise--the voluntary abortion--which remains questionable, even regrettable or repugnant for part of the public. Yet, as the majority of the Panel concluded, the use of cadaveric fetal tissue for biomedical research is "acceptable public policy" under our

current laws. This general position is essentially pragmatic: It tries to make the best out of an unhappy situation for which both the pregnant woman and a careless society are responsible. In any case, it provides the recommendations needed for setting in place regulatory and control mechanisms for a type of research that will remain highly vulnerable to public dissent, at least until truly beneficial results will be obtained.

The scientific basis for experimental therapy and other forms of biomedical research of direct health interest has been, in the meantime, considerably strengthened and enlarged.

Two Swedish Groups (A. Borklund and L. Olsen) have proceeded methodically to show that fetal transplants are viable and functional in rodents. And a group at Yale was able to demonstrate that collected brain tissue can be frozen for months without losing viability. This situation provides the researchers with the time needed to check the biochemical specificity of the tissue--which should include potential dopamine-secreting neurons--as well as the state of health of the intended graft, which should be free of either viral or bacterial pathogens. In addition, this reasonably long interval makes possible a satisfactory separation in time, space, and personnel between abortion and transplantation.

The Yale group has developed a detailed, carefully worked out protocol. Both groups--Swedish and American--have demonstrated feasibility in animal models, and the Yale group has obtained apparent cure of experimental parkinsonism in adult monkeys by transplantation of fetal monkey tissue containing potentially dopaminergic neurons. The Yale group has also succeeded in transplanting human fetal tissue in the striatum of normal monkeys and in demonstrating its survival and characteristic enzymic activity (tyrosine hydroxylase). In other words, the work has proceeded systematically, one step at a time, towards the final goal, which is transplantation of a human fetal explant taken from the appropriate region of the midbrain of a dead fetus to the part of the brain that needs dopamine-secreting neurons for its normal function in an adult human patient afflicted by parkinsonism. The final step was, in fact, performed on Thursday, December 8. Other transplantations will probably follow.

Notwithstanding the promise implied by the results of these preliminary (or preparatory) experiments, further experimentation will still be needed to define optimal conditions for each major step (tissue collection, storage, testing, and implantation) as well as for assessing the extent and the stability of clinical improvements. And the entire process will take time because of a relatively long period of latency (months) before the activity of the transplanted neurons can begin to favorably affect the disease.

The work on fetal pancreatic islets transplanted into juvenile diabetics is expected to follow similar lines; work on other diseases that may require neuron replacement is just beginning.

The Panel heard testimony of the desirability of using established cultured neuronal cell lines instead of tissue transplants, and experimentation is proceeding in this direction. Fetal cadaveric explants will still be needed to establish the cultures. And additional controls will have to be introduced to ascertain that the cells retain their specific activities in culture, in

spite of possible genotypic and phenotypic drift, and to prove that their growth can be adequately regulated in the brain. They may generate tumors.

The Panel has concentrated its attention on experimental therapeutic transplantation and has not considered other possible, biomedically important applications of fetal tissue transplants. But very recently, perhaps too recently for attracting the attention of the Panel, an important application of human fetal tissue transplantation was reported by Irving Weissman's laboratory at Stanford Medical School. The primary move came from a young M.D., Ph.D., J.D. MacClure, who--as a result of residency at the San Francisco General Hospital where he took care of AIDS patients--conceived the idea of transplanting human fetal lymphopoietic organs (thymus, lymph nodes, and liver) into mice homozygote for a severe combined immunodeficiency syndrome (SCID). These mice lack B cells and T cells; they do not reject the transplanted human cells, which establish themselves in their foreign host and produce a "hybrid" mouse (SCID/hu) provided with a human immune system.

The immediate potential use of these mice is as a convenient animal model for the study of the human acquired immunodeficiency syndrome (AIDS), but many other applications seem possible. The SCID/hu mice can allow the study of the human immune system response to other retroviruses. It can also provide an appropriate model for the study of the development of the human immune system and for exploring conditions that can prevent autoimmune disease or improve immunosurveillance against neoplastic cells. The SCID/hu mice open, in fact, much broader vistas for beneficial application than those considered in parkinsonisms or diabetes.

Dr. Windom's questions were formulated in conjunction with the current moratorium on Federal (NIH) funding of fetal research. The moratorium does not apply to research supported by private, non-Federal funds. Research done at Yale has been and continues to be supported by such funds. Therefore, legalistically, the work does not infringe on the moratorium. Why did the work of the Yale team move ahead of a decision on the moratorium instead of waiting for it? There are, I am sure, specific reasons. But we should realize that a democratic society like ours is organized in such a way as to use all possible drives and forces, altruistic or selfish, the desire to do good as well as the desire for self-promotion, greed as well as generosity, and harness them all to the slow, lumbering wagon of society's progress. Systems based entirely on idealistic considerations do not work in the long run. Sooner or later they are obliged to rediscover the virtues (or merits) of messy democracy by democratization.

Of course we should take advantage of this diversity of motivations and put them to work. But at the same time a reasonable regulatory system is definitely advisable to prevent abuse, to set standards, and to maintain quality. The NIH should enter the field for two reasons: The field is clearly promising--more promising than we believed a few months ago. And a regulatory system is needed given the sensitivity of part of the public in such matters. The NIH already has functioning mechanisms for quality control--scientific, ethic, and otherwise--of the research it supports. The NIH can set standards that will be followed by other agencies. It can also have power of enforcement as it has in the case of affirmative action. And it has the experience of reasonable and adaptable regulatory activity acquired in relation to recombinant DNA experimentation.